

AMENDMENTS TO THE DRAWINGS

Appended hereto as attachments are replacement drawing sheets for sheets 2, 3, and 4 of the drawings, to replace the corresponding drawing sheets that were included in the application as filed and as examined. The attached replacement drawing sheets have each been amended to correct the spelling of "forskohlii."

Also appended hereto are copies of the drawings as filed showing in red the amendments that are reflected on the attached replacement drawing sheets.

REMARKS

The specification and drawings have each been amended in several respects to respond to the several informalities that were referred to by the examiner. In that regard, the trademark SSNIFF[®] has been capitalized in paragraph [0079] of the specification when it is referred to in its trademark sense, but that term has not been capitalized when it is used as a part of the corporate name included in that paragraph, because the owner of that corporate name includes that term in lower case letters.

Claims 1-3, 5-8, and 17 were objected to on the ground of spelling informalities. Each of those claims has been amended to correct the misspellings that were noted by the examiner. Corresponding spelling corrections have also been made to several paragraphs of the specification and to several sheets of the drawings. None of the amendments to the specification or to the drawings introduces new matter.

Claims 1-3, 5-8, and 17 were rejected as indefinite. Each of the instances of alleged indefiniteness has been addressed in the foregoing claim amendments, and it is believed that those claim amendments overcome the indefiniteness rejections.

Claims 1, 3, 5-8, and 17 were rejected as obvious based upon the combination of the disclosures contained in the Liao et al. '749, the Majeed et al. '596, the Gow et al. '184, the de la Harpe et al. '888, and the BE '545 references. It was concluded that one of only ordinary skill in the art would be able from the references to arrive at the claimed invention. And claim 2 was rejected as obvious based upon that same combination of references, along with the Chokshi '403 reference.

Although the references individually mention respective ones of the constituents of the combination of constituents of the present invention, each individual reference

mentions only a single constituent of the invention, not any combination of as few as even two of the constituents. In that regard, however, it should be noted that although the Majeed et al. reference mentions a forskohlin extract, it does not disclose a *coleus forskohlii* extract containing at least 10 % by weight of diterpene forskohlin, as is recited in claim 1. And neither of the other references relied upon discloses or suggests either the inclusion of that constituent or its amount in any particular combination of constituents.

With regard to the combination of the separately-disclosed constituents, it was concluded at page 7 of the Action that, "No patentable invention resides in combining old ingredients of known properties where the results obtained are no more than the additive effect of the ingredients." But as shown in the present application in Figs. 2A and 2B, the individual constituents green tea extract, *coleus forskohlii*, Yerba Maté, and *Betula Alba* each individually provides substantially the same effect as the other individual constituents on body weight increase and on the mean rate of change of body weight of tested rats. In Fig. 2A there is shown the increase in body weights of the tested rats that were fed only individual constituents of the claimed invention, and at the end of 12 weeks the effect of each individual constituent was within the narrow range of from about 42% to about 46%, whereas the corresponding increase for the claimed composition was significantly lower at about 32%. Those data for the individual constituents would not lead one to combine any of them because one of ordinary skill in the art would conclude that no different effect would be produced by any such combination.

Similarly, Fig. 2B shows the mean change in body weights of the tested rats fed

only individual constituents of the claimed invention, and at the end of 3 months each change was within the narrow range of from about 71% to about 79%, whereas the change over that same time interval for the claimed composition was significantly lower at 60%. Those data for the individual constituents would, again, not lead one to combine any of them because one of ordinary skill in the art would conclude that no different effect would be produced by any such combination. It is noteworthy that none of the references contains any information that would suggest any synergistic effect from any combination of the constituents as claimed. Indeed, none of the references even remotely suggests any combination of the claimed constituents. And the present application provides ample evidence of the synergistic effect of the claimed invention by virtue of the examples and the tables that are included in the specification, along with Figs. 2A and 2B of the drawings, as pointed out above.

It was acknowledged in the Action, in the paragraph bridging pages 7 and 8, that, "The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize." But as stated in MPEP § 2143.01, III., "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art." (Emphasis in original) (citing the *KSR* case). There is no basis for concluding predictability where a composition includes five different constituents, each present in the composition in specific and varying amounts. It is suggested that the optimization conclusion could more plausibly be advanced were there only two constituents in the combination. The

presence of five different constituents, each of which is mentioned in a different reference, would require a virtually limitless number of optimization trials involving many different variations of the amounts of each of the individual constituents, while maintaining the amounts of other constituents constant, and that would each then be subjected to animal testing to ascertain their effectiveness in achieving the expected synergistic result. Clearly, such a testing program would be a hopelessly complex task, one that would be impractical from both a financial and a time standpoint, and would therefore not even be attempted by one of ordinary skill in the art. As also stated in the MPEP, at § 2141.02 I., "In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." (Emphasis in original). Considering the invention as a whole as it is claimed in claim 1, the claimed invention would not be obvious to one of ordinary skill in the art having before him or her the references that were relied upon.

Claims 2, 3, 5-8, and 17 each depend from claim 1, either directly or indirectly, and therefore those dependent claims are also not obvious based upon the combinations of references that were relied upon by the examiner. Additionally, the dependent claims contain further recitations that distinguish the so-claimed invention from the combinations of references.

The claimed invention has already been patented in Europe. A copy of the English-language version of the claims that were granted in Europe (EP 1 708 726 B1, granted October 15, 2008) is attached, along with a copy of the first page of that document. Consequently, the invention as claimed in the European application was

concluded to have satisfied each of the novelty, inventive step, and industrial applicability criteria of the European Patent Convention.

Based upon the foregoing amendments and remarks, the amended specification is no longer objectionable, and the claims as they now stand in the application are believed clearly to be in allowable form. The claims patentably distinguish over the combinations of the disclosures contained in the several references that were cited and relied upon by the examiner as support for a rejection under 35 USC 103. Consequently, this application is believed to be in condition for allowance, and reconsideration and reexamination of the application is respectfully requested with a view toward the issuance of an early Notice of Allowance.

Should the examiner have any question after considering this Amendment, she is cordially invited to telephone the undersigned attorney so that any such question can be quickly resolved in order that the present application can proceed toward allowance.

Respectfully submitted,



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Attachments: Replacement drawing sheets including changes
Annotated drawing sheets showing the changes
Pages 1, 7, and 8 of EP 1 708 726 B1